

June 16, 2020

A MESSAGE FROM THE PRESIDENT OF ETHICS

Dear ETHICS members – Welcome to our Sixth Special Edition of ETHICS In Action. This edition focuses on Lessons Learned during this phase of the COVID 19 Pandemic. We would like to thank Sue Egan for preparing this edition in cooperation with our editor, John McLoughlin.



Roeland Van Aelst

Do not miss our next COVID 19 WEBINAR which will be held on Tuesday, June 23rd (see below to register).

**THE NEXT ETHICS COVID 19 WEBINAR WILL TAKE PLACE
ON TUESDAY JUNE 23rd at 16h30 CET. The topic is:
ETHICS AND COMPLIANCE LESSONS LEARNED TO DATE DURING
THE COVID PANDEMIC**

Registration is free. You may invite colleagues to join. Click on the link below to register:
<https://www.eventbrite.fr/e/billets-ethics-webinar-4-on-covid-19-lessons-learnt-from-the-pandemic-109006503386>

LESSONS LEARNED

Introduction

The current COVID-19 emergency has forced healthcare companies to take rapid action in order to respond to urgent customer and staff requirements. Some companies have found that their policies, procedures and / or business continuity plans were not adapted to situations which arose during the pandemic. As we begin to return to business as usual, some companies will find that there have been instances of non-compliance during the pandemic, often simply due to the lack of normal structure and routine, or because key personnel were not available. It is possible that resolving the instances of non-compliance will present a large workload for Ethics and Compliance staff. Some thought will be needed to understand how this can be done efficiently. Furthermore, it will be useful to review how the interaction between Ethics and Compliance officers and other colleagues in their organizations held up during the pressures of the crisis. Reflecting on these relationships may reveal that the lockdown due to the pandemic may have been beneficial for some relationships and detrimental to others.

Finding and Correcting Instances of Non-Compliance

Many Ethics and Compliance teams are already receiving voluntary reports from their colleagues to let them know about instances where policies and procedures were not fully followed during the pandemic. Some effort may be needed to discover other instances of non-compliance that may have been missed in the confusion of the last few months.

Company employee reporting lines, monitoring, and auditing activities are all good sources for identifying instances of non-compliance. During the next few months, it may be necessary to increase monitoring and auditing activities and to encourage staff to report incidents via employee reporting lines. Once incidents are reported or discovered, the company's procedure for managing such events should be applied based on a triage system of the most urgent need first. For companies which do not already have a procedure for investigating instances of non-compliance and managing corrective actions, here are some headings that such a procedure should normally include:

1. Verifying the facts – is the report credible / might there be another point of view that differs from the original report? Who can help to verify the facts?
2. Understanding the severity of the non-compliance – is it minor, medium, or major? Is it a breach of internal policy, of external codes, and / or of local or international law? Does the breach involve risk of harm to patients?
3. Finding the root cause(s) of the non-compliance – it is vital to understand the root cause(s) of the breach before determining what corrective action needs to be taken. Was this an isolated instance due to the pandemic? Were the internal policies and procedures inadequate for this situation? Had the person been trained in the relevant procedure(s)? Did they simply panic due to the urgency of the situation?
4. Understanding what corrective action(s) need(s) to be taken – the answers to the previous two questions will determine who else inside and outside the company needs to be informed, for example the divisional head, CEO, regulators and / or industry associations. In cases where external codes of practice and / or laws have been breached, it may be necessary to contact the relevant authorities outside the company *before* the root causes are fully understood. There may have been previous instances of similar non-compliance that could inform decisions on corrective actions. Note that corrective action may simply be re-training for one person or a whole team, and / or updating the relevant policy or procedure followed by re-training – it does not necessarily involve disciplinary action.
5. Taking action and documenting that action – it is important to close each incident appropriately and to ensure that the relevant internal Ethics and Compliance Committee understands each incident to an appropriate level of detail so that appropriate actions can be taken across the company.

Non-compliance with Internal Policies and Standard Operating Procedures (SOPs)

Many companies have already stated that their internal policies and procedures around grants and donations were not adapted to deal with problems which arose during the pandemic. Other policies and procedures may also have been found to be inappropriate during the crisis, possibly because the usual decision-makers were not readily available or because the normal forms could not be used. The task of “cleaning up” and / or completing compliance documentation and files that were not managed in the normal manner due to the emergency will typically fall on those

responsible for each SOP but Ethics and Compliance staff may need to be involved in determining the relevant course of action.

The period of post-pandemic correction should be an opportunity for companies to review their internal policies and especially their SOPs. In addition to looking at those SOPs that did *not* work well during the pandemic, it will be beneficial to explore those that *did* work well. Understanding why certain SOPs were effective may enable companies to apply some valuable lessons to those SOPs that were not. What is it about the successful SOPs that made them successful and how can these positive characteristics be implemented across the organization?

In reviewing SOPs, companies may find that some tend towards being “rules-based” while others tend more being “values-based”. Rules-based SOPs will contain statements such as “these roles must do this, then this, then pass the item on to those roles who must do that, then ...”. Values-based SOPs will contain statements such as “the desired outcome of this SOP is ..., which may be achieved by at least two persons from these roles doing ...”. The rules-based example tends to be highly prescriptive with specific actions needed to be taken at specific points in the process by specified individuals and may run to 50 or more pages. This type of SOP is well suited to research operations and manufacturing operations where consistency is vital to the quality of the finished product. The values-based example tends to offer ways of achieving an outcome and are well suited to sales and marketing operations where there may be more judgement involved in decision-making. It should be noted that values-based SOPs must be supported by an appropriate culture and regular training to ensure that everyone understands the values on which decisions are to be made.

Where the correct SOP forms could not be used, the most obvious solution is to have the relevant person complete and submit the correct form as soon as possible after the event with the original information so that continuity is preserved. Another solution might be to update the relevant SOP to be more flexible on the use of a specific form in order to increase the likelihood that the original information will be filed in a timely manner rather than emphasizing the use of the “correct” form. Before determining which course to follow, care should be taken to understand whether the form is for internal use only or is a requirement of an external body, such as Pharmacovigilance forms submitted to the relevant competent authority. In the latter case it may be a requirement to use a specific form, which may need to be completed online or offline before submission.

Compliance Lite (or Light)

Some organizations are discussing potential reductions in governance and / or compliance oversight of some processes (for example grants and donations) that have been implemented during the pandemic and making them part of the organization’s SOPs going forward. Others are considering again the topic of “compliance lite” that has been discussed on and off for many years. It is possible that some organizations have too much oversight in some areas and not enough in other areas. Each suggested reduction in compliance oversight should be viewed both individually and within the overall context of organizational risk to understand whether the proposal is likely to increase risk. Balancing factors may include activities undertaken by the Ethics and Compliance Committee.

It is possible that extra oversight can lead to an increased risk of non-compliance as everyone in the process relies on everyone else to reduce risk. An example is a document which requires

many signatures. This may actually reduce the probability that each signatory will read the whole document as they all rely on each other to have read it fully.

Each Ethics and Compliance team member should regularly review their own areas to understand whether they are too involved or not involved enough in each process, and whether the organization is mature enough to enable reduced oversight of a particular process at this moment. If not, how will we know when the organization *is* ready? Are there some criteria that can be applied to each process that, when met, will enable us to know that our colleagues have the process under control and no longer need detailed oversight?

A “compliance lite” approach will help to reduce risk within appropriate processes in a mature organization but will increase risk in inappropriate processes and / or immature organizations. We need to be alert to the risks and ensure that any decisions to reduce oversight are taken for the right reasons and using appropriate facts.

Business Continuity Plans (BCPs)

Many companies will have found that their business continuity plans *were* fit for purpose and effective during the pandemic. Others may have found that their BCPs were *not*, possibly because they were too detailed and so could not be followed to the letter, or they were not detailed enough, or because they relied on key personnel who were not available at key moments. The responsibility for developing and managing BCPs usually sits outside the Ethics and Compliance team, so is unlikely to be high on our list of issues to manage post-pandemic. However, as with policies and procedures, it is likely that Ethics and Compliance officers will need to be involved in actions to resolve non-compliance.

Companies will need to understand whether their BCP was sufficiently adapted to the crisis and if not, what was missing or what went wrong? If any company does not have a Business Continuity Plan, they should urgently consider whether to put one in place, even if all it includes is a list of names, roles and contact details for key decision-makers in a crisis.

Relationships

Successful Ethics and Compliance officers must have effective professional relationships with colleagues throughout their organizations. Much of our work is managed through others, or is done to resolve situations where individuals are not able to handle a situation and need our help, so the value of these relationships is vital to our success and our organizations’ success.

Video conferences cannot fully substitute for physically being in the same place with other people. It is likely that some previously effective professional relationships have been strained during the lockdown, while others will have begun or been improved during this time.

The lockdown has, however, presented an opportunity to build positive relationships based on our shared situation - focusing on what we have in common is a great way to build these positive relationships. Whilst everyone’s experience of lockdown has been different due to individual circumstances, the fact that most of us have been confined to our homes has created a shared experience.

Ethics and Compliance officers should reflect on those relationships during lockdown in order to understand what made them better or worse. Was there something different about being in

lockdown that can be taken forward as organizations re-open offices? Did we behave differently? Are there some relationships that had been neglected prior to and / or during lockdown that now need to be nurtured? Which relationships are vital to our success within the organization and should therefore be improved going forward?

Conclusion - Lessons Learned

Every company is different and will have different experiences of the pandemic due to their culture, size, maturity of their compliance programs, and other factors. Each company will therefore have different lessons to learn, but hopefully some of the key questions to be asked have been highlighted in this Special Edition of ETHICS in Action.

If you have ideas, experiences or compelling stories which could help your colleagues and that you would like to share with other ETHICS members relating to the impact of COVID 19 on ethics and compliance, please let us know by contacting the ETHICS In Action editor, John McLoughlin, at john.mcloughlin.ethics@gmail.com

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